

Dolisos

A Leader In Worldwide Homeopathy

December 1, 1997

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center For Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St., S.W. (HFS-450)
Washington, D.C. 20204

1604 '98 FEB 18 1998
DEC 15 1997

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Dolisos America, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Passion Flower. The statement of nutritional support reads as follows:

To maintain normal sleep rhythm.

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful, and non-misleading.

Sincerely,



William Nicoletti, R. Ph.
President

975-0162